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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,813	01/03/2007	Stephen John Ralph	DAVI271.001APC	5240

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EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
10/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/575,813	RALPH, STEPHEN JOHN	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *10,12 and 46-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11 and 13-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-45 in the reply filed on July 29, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Additionally, Applicants have elected species as follows: Lectin: C-lectin; Lectin-interactive agent: disaccharides; and carbohydrate: thiodiagalactoside. Claims 1-9, 11 and 13-45 read on the elected species. Accordingly, claims 1-9, 11 and 13-45 are under consideration in the instantly filed application, and claims 10, 12 and 46-52 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

3. Claims 1-9, 11 and 13-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-9, 11 and 13-45 recite a "lectin interactive agent" and "an immune modulating agent."

The specification and claims do not indicate what distinguishing attributes are

shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "lectin interactive agent/immune modulating agent" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. There is no teaching regarding any structural property which is retained by agents which have the ability to interact with lectin, or agents which can modulate the immune system and "correspond to at least a portion" of a target antigen. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description

provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, the guidelines can be found at the following link on the USPTO Internet in "Patents Guidance" Specifically, Example 10, which is analogous to the claimed product identified by a particular function.

<http://www.uspto.gov/web/patents/guides.htm>

2. Claims 1-9, 11 and 13-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "corresponds to at least a portion of the target antigen." For instance, what minimum structure is considered at least a portion (e.g., 50%, 10%, single amino acid)? Furthermore, once this minimum determinant is understood, what level of correspondence is then required (100%, 90%, 40%, etc), or can the fact that the instantly claimed protein is made from the same 20 amino acids as the target antigen be considered corresponds to at least a portion? Without a clear definition as to the metes and bounds of the phrase "corresponds to at least a portion of the target antigen" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "synthetic or semisynthetic analogue thereof." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance what amount of derivation is allowed to still be considered an analogue? Similarly at what point is the molecule sufficient altered to no longer be considered an analogue? Without a clear definition as to the metes and bounds of the term analogue one of skill in the art would be unable to determine the metes and bounds of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9, 11 and 13-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Figdor et al.

The claims are directed to a composition for modulating an immune response to a target antigen, comprising a lectin-interactive agent and an immune-modulating agent selected from the group consisting of an antigen that corresponds to at least a portion of the target antigen, an antigen binding molecule that is immunoreactive with the target antigen and an immuno-modulating cell that modulates an immune response to the target antigen, wherein the lectin-interactive agent and the immune-modulating agent are not conjugated with other chemical moieties.

Figdor et al (WO 00/63251) disclose of a composition of a compound that binds to a C-type lectin and an antigen. (See abstract and claims 7 and 9).

Given that Figdor et al disclose of a composition comprising a lectin interactive agent (compound which binds C type lectin) and an immune-modulating agent (tumor antigens, infectious disease antigens), the disclosure of Figdor et al is deemed to anticipate the instantly filed claims.

5. Claims 1-9, 11 and 13-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Nedwin et al.

The claims are directed to a composition for modulating an immune response to a target antigen, comprising a lectin-interactive agent and an immune-modulating agent selected from the group consisting of an antigen that corresponds to at least a portion of the target antigen, an antigen binding molecule that is immunoreactive with the target antigen and an immuno-modulating cell that modulates an immune response to the target antigen, wherein the lectin-interactive agent and the immune-modulating agent are not conjugated with other chemical moieties.

Nedwin et al (US Patent Number 5,587,460) disclose of a composition containing purified 14 kDa lectins and thiodigalactoside. (See Example 7).

Given that Nedwin et al disclose of a composition comprising a lectin interactive agent (thiodigalactoside) and an immune-modulating agent (14 kDa lectins), the disclosure of Nedwin et al is deemed to anticipate the instantly filed claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
October 8, 2009